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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,589	07/30/2001	Cale M. Halbleib	Pan Vera.017.01	2015

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/918,589

Applicant(s)

HALBLEIB ET AL.

Examiner

Joseph F. Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-20, 22 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-20, 22, 24-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05242005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Formal Matters***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/24/2005 has been entered.

Claims 16-20, 22, 24-31 are pending and under consideration.

### ***Response to Amendment***

The objection to claims 26-28 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim has been withdrawn.

The rejection of claim 23 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, has been rendered moot by cancellation of the claim and is thus withdrawn.

The rejection of claim 20, 29 under 35 U.S.C. 112, first paragraph, as lacking enablement, has been withdrawn based on Applicant's arguments.

The rejection of claims 20, 29 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, has been withdrawn based on Applicant's arguments.

The rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been rendered moot by cancellation of the claim and is thus withdrawn.

The rejection of claims 16-22, 24-25, under 35 U.S.C. 102(b) as being anticipated by WO 99/27365 (Lustig et al.) in view of U.S. Patent No. 6,248,520 (Roeder et al.), and further in view of in view of U.S. Patent No. 6,054,295, has been withdrawn based on Applicant's arguments.

New issues are set forth below.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 16-20, 22, 24-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,876,946 (Burbaum et al.) in view of U.S. Patent No. 6,248,520 (Roeder et al.), and further in view of in view of U.S. Patent No. 6,054,295.

The claims are drawn to methods of monitoring binding reactions between fluorescently labeled ligands and nuclear hormone receptor in the presence of test compounds, and measuring the results by measuring fluorescent polarization. The claims are unpatentable because the '946 patent discloses high throughput screening of compounds, such as those found in combinatorial libraries, to determine active drug candidates. (Column 3, lines 37-40). a cell with attached receptors ('Y'), as they bind to fluorescently-labelled ligands (solid square flagged with 'F'). In FIG. 1C, fluorescently-labelled ligands are displaced by library compound (open triangles). FIGS. 1B and 1D schematically indicate fluorescence collected from sections of samples with and without active library compounds, respectively. Presence of a "spot" relative to background fluorescence indicates bound ligand, while the background fluorescence itself results from free ligand. (Column 4, line 65 to column 5, line 5). In addition the '946 patent discloses that nuclear receptors, such as steroid receptors, are advantageously expressed recombinantly, and employed in the microbead assay of the invention. (Column 7, lines 8-15).

The '946 patent differs from the claims in that it does not teach the method wherein the receptor is GR, AR or PR, or wherein the LBD is bound to GST. However, the '520 patent discloses methods of screening for compounds which act as antagonists for steroid hormones where in the hormone receptor is androgen receptor (AR) glucocorticoid receptor (GR) or progesterone receptor (PR) ('520 at column 12, line 55 to column 13, line 5). Additionally, the '295 patent discloses fusion constructs expressing both full length nuclear receptors fused to

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GST coding sequences, as well as ligand binding domains of nuclear hormone receptors fused to GST ('295 at column 14 ,lines 5-20). Therefore it would have been obvious to one of skill in the art at the time the invention was made to practice a method of screening for modulators of nuclear hormone receptor function comprising measuring the binding of a sensor polypeptide at sub-micromolar concentrations to a nuclear hormone receptor in the presence of a candidate agent, and comparing the result to a control by measuring the fluorescence polarization of the solution of the solution and comparing the fluorescence polarization of the solution in the presence and absence of the compound to indicate any competitive interaction, wherein the receptor is GR, AR or PR, or wherein the LBD is bound to GST. The motivation and expectation of success is provided in the '946 patent which discloses that he support may also be coated with a recombinantly produced receptor, or receptor binding domain. This is particularly advantageous for receptors or domains that are not normally expressed on the cell surface. For example, nuclear receptors, such as steroid receptors, are advantageously expressed recombinantly, and employed in the microbead assay of the invention. (Column 7, lines 8-15).

### *References*

The Office will no longer be supplying paper copies of U.S. Patents cited in Office Actions. Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources. Applicant may direct inquiries about the use of the Office's PAIR system to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

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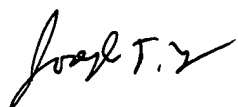
***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.  
Primary Examiner  
Art Unit 1646  
July 26, 2005

  
**JOSEPH MURPHY**  
**PATENT EXAMINER**